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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,845

02/04/2004

Andrew G.C. Frazier

MVMDINC.019A

9741

68716

7590

09/12/2008

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

PAPER NUMBER

3773

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09/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/771,845	<b>Applicant(s)</b> FRAZIER ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-13, 15, 16 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-13, 15, 16 and 48-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/13/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This office action is in response to claims filed 6/13/08.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7,10-13,15,16,48-56 are rejected under 35 U.S.C. 103(a) as obvious over Shaw et al. (U.S. Patent No. 6,080,182).

Shaw teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum (Figs. 7A,7B), comprising:

- providing a closure device having a proximal end (182), a distal end (183), a proximal segment (182), an intermediate segment (202) and a distal segment (183), the proximal and intermediate segments defining a first clip-shaped portion (112) and the intermediate and distal segments defining a second clip-shaped portion (left portion of 201 in Fig. 32A), wherein the closure device is self-expandable to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel to one another (Fig. 32A)
- deploying the closure device within the patent foramen ovale (Fig. 7,32C) such that the second clip-shaped portion is positioned over a tip of the

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septum primum and the first clip- shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in a channel between the septum primum and the septum secundum

- locking the position of the proximal segment, the intermediate segment and the distal segment of the closure device after deployment with a locking element (removal of 152 causes the element to lock, as the element has shape memory and automatically locks onto the tissue after removal of element 152) that is separate from the proximal segment, intermediate segment and the distal segment
- wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (Fig. 7,32C)
- the intermediate and distal segments of the closure device when deployed are positioned along surfaces of the septum primum and the proximal and intermediate segments of the closure device when deployed are positioned along surfaces of the septum secundum (Fig. 7,32C)
- the first clip-shaped portion and second clip-shaped portions are integrally formed (Fig. 32A)
- the first clip-shaped portion and second clip-shaped portions are made of wire (Fig. 32A)
- the first clip-shaped portion and second clip-shaped portions when the device is deployed forms generally an S-shape (Fig. 32A)

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- each clip-shaped portion is formed from two adjacent loops connected by a connecting portion (Fig. 32A)
- deploying the closure device comprises releasing the closure device from a detachment element provided on the device (200)
- the closure device is held in its elongate configuration distal to a deployment catheter (210, Fig. 36)
- the closure device is delivered by positioning a catheter between the septum primum and septum secundum (Figs. 7A,32C)
- the closure device includes a plurality of eyelets (183,212,182), and the closure device is releasably attached to the delivery device
- the intermediate segment comprises at least two side-by-side wire portions (201)
- the locking element is provided as part of the closure device (Fig. 32B, 152 is part of the closure device)
- the locking element connects to the proximal and distal ends of the device, and locking the position of the closure device after deployment comprises longitudinally shortening and radially expanding the device (Fig. 32C)
- the locking element remains within the patent foramen ovale upon deployment (Fig. 32B)
- the locking element comprises a locking string (152 is considered a string, as the applicant does not provide structure for the string, and 152 can be considered a string) connected to eyelets provided on the closure device.

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Shaw teaches the claimed invention including using the device with heart defect, but fails to specify the type of heart defect including a patent foramen ovale (PFO), however it is well known in the art that a PFO is a heart defect, and Shaw specifically teaches using the device on heart defects, as shown in the figures of Shaw. It would have been obvious to one of ordinary skill in the art to use the defect of Shaw with a PFO as it is well known in the art that a PFO is a common defect.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR  
/Melissa Ryckman/  
Examiner, Art Unit 3773

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/Darwin P. Erezol  
Primary Examiner, Art Unit 3773